

Case Docket No. NIH211.001C1

Date: February 20, 2004

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)

Moss et al.

Appl. No.

10/646,628

Filed

August 22, 2003

For

**MVA EXPRESSING** 

MODIFIED HIV ENVELOPE,

GAG, AND POL GENES

Examiner

Unknown

Group Art Unit:

1645

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

February 20, 2004

(Date)

Nancy W. Vensko, Reg. No. 36,298

## TRANSMITTAL LETTER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are:

- (X) An Information Disclosure Statement.
- (X) A PTO Form 1449 with twenty-eight (28) references.
- (X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.

Nancy W. Vensko Registration No. 36,298 Attorney of Record

Customer No. 20,995

(805) 547-5580

## INFORMATION DISCLOSURE STATEMENT

Applicant

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed is form PTO-1449 listing 28 references.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required in accordance with 37 C.F.R. § 1.97(b)(3). If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated:

By:

Nancy W Vensko

Registration No. 36,298

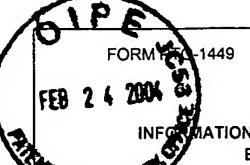
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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY, DOCKET NO. NIH211.001C1 APPLICATION NO. 10/646,628

MATION DISCLOSURE STATEMENT
BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT Moss et al.

FILING DATE August 22, 2003 GROUP 1645

	U.S. PATENT DOCUMENTS						
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	1.	5,849,304	12/15/1998	Moss et al.			
	2.	5,185,146	02/09/1993	Altenburger			

	FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	- CLASS	SUBCLASS	TRANS YES	LATION
	3.	WO 01/47955 A2	07/05/2001	PCT				

EXAMINER INITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
`	4.	Allen, T.M. et al., 2000 "Induction of AIDS virus-specific CTL activity in fresh, unstimulated peripheral blood lymphocytes from rhesus macaques vaccinated with a DNA prime/modified vaccinia virus Ankara boost regimen" J. Immunol. 164:4968-4978.
	5.	Amara, R.R. et al., 2001 "Control of a Mucosal Challenge and Prevention of AIDS by a Multiprotein DNA/MVA Vaccine" Science 292: 69-74.
	6.	Barouch, D.H. et al., 2000 "Control of viremia and prevention of clinical AIDS in rhesus monkeys by cytokine-augmented DNA vaccination" <i>Science</i> <b>290</b> :486-492.
1	7.	Egan, M.A. et al., 2000 "Simian immunodeficiency virus (SIV) gag DNA-vaccinated rhesus monkeys develop secondary cytotoxic T-lymphocyte responses and control viral replication after pathogenic SIV infection" J. Virol. 74:7485-7495.
	8.	Gomez, C.E et al., 2001 "Recombinant proteins produced by vaccinia virus vectors can be incorporated within the virion (IMV form) into different compartments" <i>Arch Virol.</i> 146(5):875-892.
r	9.	Gorelick, R.J. et al., 1999 "Nucleocapsid protein zinc-finger mutants of Simian Immunodeficiency Virus strain Mne produce virions that are replication defective in vitro and in vivo" Virology 253:259-270.
•	10.	Goulder, P.J. et al., 1999 "Anti-HIV cellular immunity: recent advances towards vaccine design" AIDS (Suppl. A) 13:S121-S136.
,	11.	Hirsch, V.M. et al., 1995 "Limited virus replication following SIV challenge of macaques immunized with attenuated MVA vaccinia expressing SIVsm env and gag-pol" Vaccines 95:195-200.
i	12.	Hofmann-Lehmann, R. et al., 2000 "Sensitive and robust one-tube real-time reverse transcriptase-polymerase chain reaction to quantify SIV-RNA load: comparison of one- versus two-enzyme systems" AIDS Res. Hum. Retroviruses 16:1247-1257.

EXAMINER	DATE CONSIDERED

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FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. NIH211.001C1	APPLICATION NO. 10/646,628	
	DISCLOSURE STATEMENT Y APPLICANT	APPLICANT Moss et at.		
(USE SEVERAL	L SHEETS IF NECESSARY)	FILING DATE August 22, 2003	GROUP 1645	

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)				
•	13.	Karacostas, V. et al., 1989 "Human immunodeficiency virus-like particles produced by a vaccinia virus expression vector" <i>PNAS USA</i> 86:8964-8967.			
	14.	Karlsson, G.B. et al., 1997 "Characterization of molecularly cloned simian-human immunodeficiency viruses causing rapid CD4 <sup>+</sup> lymphocyte depletion in rhesus monkeys" <i>J. Virol.</i> 71:4218-4225.			
•	15.	Lechner, F. et al., 2000 "Analysis of successful immune responses in persons infected with hepatitis C virus" <i>J. Exp. Med.</i> 191:1499-1512.			
	16.	Mellors, J.W. et al., 1996 "Prognosis in HIV-1 infection predicted by the quantity of virus in plasma" Science 272:1167-1170.			
i	17.	Montefiori, D.C. et al., 1998 "Neutralizing antibodies in sera from macaques infected with chimeric Simian-Human Immunodeficiency Virus containing the envelope glycoproteins of either a laboratory-adapted variant or a primary isolate of Human Immunodeficiency Virus type 1" <i>J. Virol.</i> 72:3427-3431.			
ì	18.	Montefiori, D.C. et al., 1988 "Evaluation of antiviral drugs and neutralizing antibodies to Human Immunodeficiency Virus by a rapid and sensitive microtiter infection assay" <i>J. Clin. Microbiol.</i> <b>26</b> :231-235.			
	19.	Moss, B. et al., 2000 "Retroviruses of human AIDS and related animal diseases" in: Colloque des Cent Gardes, 12th, Paris, France, Oct. 25-27, 1999, Meeting Date 1999, 105-107, Eds. M. Girard & B. Dodet, Editions Scientifiques et Medicales Elsevier, Paris, Fr. (Abstract).			
	20.	Ourmanov I. et al., 2000 "Recombinant modified vaccinia virus Ankara expressing the surface gp120 of simian immunodeficiency virus (SIV) primes for a rapid neutralizing antibody response to SIV infection in macaques" <i>J Virol.</i> 74:2960-2965.			
	21.	Ourmanov, I. et al., 2000 "Comparative efficacy of recombinant modified vaccinia virus Ankara expressing Simian Immunodeficiency Virus (SIV) Gag-Pol and/or Env in macaques challenged with pathogenic SIV" J. Virol. 74:2740-2751.			
	22.	Power, C.A et al., 1999 "A valid ELISPOT assay for enumeration of ex vivo, antigen-specific, IFNγ-producing T cells" J. Immunol. Methods 227:99-107.			
	23.	Quinn, T.C. et al., 2000 "Viral load and heterosexual transmission of Human Immunodeficiency Virus type 1" N. Engl. J. Med. 342:921-929.			
	24.	Robinson, H.L. et al., 2000 "AIDS Vaccines: heterologous prime/boost strategies for raising protective T cell responses" AIDS Rev. 2:105-110.			
	25.	Robinson, H.L. et al., 1999 "Neutralizing antibody-independent containment of immunodeficiency virus challenges by DNA priming and recombinant pox virus booster immunizations" <i>Nature Med.</i> 5:526-534.			
	26.	Sauter, M.M. et al., 1996 "An internalization signal in the Simian Immunodeficiency Virus transmembrane protein cytoplasmic domain modulates expression of envelope glycoproteins on the cell surface" <i>J. Cell Biol.</i> 132:795-811.			

EXAMINER	DATE CONSIDERED	

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	FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. NIH211.001C1	 APPLICATION NO. 10/646,628	
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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)			
ŧ	27. Staprans, S. et al., 1996 "Quantitative methods to monitor viral load in Simian Immunodeficien infections" in: <u>Viral Genome Methods</u> , K. Adolph, Ed. (CRC Press, Boca Raton, FL, 1996), pp.			
	28.	Waldrop, S.L. et al., 1997 "Determination of antigen-specific memory/effector CD4 <sup>+</sup> T cell frequencies by flow cytometry: evidence for a novel, antigen-specific homeostatic mechanism in HIV-associated immunodeficiency" J. <i>Clin. Invest.</i> <b>99</b> :1739-1750.		

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